REMARKS

Pending claims

Claims 1-20 have been canceled, and Claims 21-40 have been added.

New Claims 21-29, 31-32, and 36-37 correspond to the original claims of Group I (Claims 1-6 and 9-15, now canceled). New Claims 33-35 correspond to the original claims of Group II (Claims 7-8, now canceled). New Claim 30 corresponds to the original claim of Group III (Claim 16, now canceled). New Claims 38-40 are drawn to methods of use of the polypeptides of Group I. Claims corresponding to the original claims of Groups IV, V, VI, and VII (Claims 17, 18, 19, and 20, now canceled) have not been reiterated herein.

Restriction Requirement

In the Restriction Requirement, the Examiner requested Applicants to elect one of the following inventions:

Group I (Claims 1-6 and 9-15) drawn to a purified polypeptide, the polynucleotide encoding it, an expression vector comprising said polynucleotide, a host cell comprising said vector, a method for producing the encoded polypeptide;

Group II (Claims 7-8) drawn to a method for detecting a polynucleotide;

Group III (Claim 16) drawn to a purified antibody;

Group IV (Claim 17) drawn to a purified agonist;

Group V (Claim 16 [*sic*: Claim 18]) drawn to a purified antagonist;

Group VI (Claim 19) drawn to a method for treating or preventing a disorder by administering a pharmaceutical composition; and

Group VII (Claim 20) drawn to a method for treating or preventing a disorder by administering an effective amount of an antagonist.

Applicants hereby elect, with traverse, to prosecute Group I, which includes and is drawn to Claims 21-29, 31-32, and 36-37 (corresponding to Claims 1-6 and 9-15, now canceled). Further, Applicants elect, with traverse, to prosecute that portion of Claims 21-29, 31-32, and 36-37 directed to the polypeptide sequence of SEQ ID NO: 5 and the polynucleotide sequence of SEQ ID NO:14. Applicants traverse both the restriction requirement among the Groups and that among the individual sequences for at least the following reasons.

Applicants reserve the right to prosecute the subject matter of non-elected claims in subsequent divisional applications.

The unity of invention standard ***must*** be applied in national stage applications

Section 1850 of the Manual of Patent Examining Procedure (original 8th edition, published August, 2001) (hereinafter "MPEP") provides:

> ... [W]hen the Office considers international applications ... during the national stage as a Designated or Elected Office under 35 U.S.C. 371, PCT Rule 13.1 and 13.2 will be followed when considering unity of invention of claims of different categories without regard to the practice in national applications filed under 35 U.S.C. 111....
>
> In applying PCT Rule 13.2 to ... national stage applications under 35 U.S.C. 371, examiners should consider for unity of invention all the claims to different categories of invention in the application and permit retention in the same application for searching and/or preliminary examination, claims to the categories which meet the requirements of PCT Rule 13.2....

Id at page 1800-60 to -61.

MPEP section 1893.03(d) reiterates the Examiner's obligation to apply the Unity of Invention standard PCT Rule 13.2 instead of U.S. restriction/election of species practice:

> Examiners are reminded that unity of invention (not restriction) practice is applicable ... in national stage (filed under 35 U.S.C. 371) applications.

Id at page 1800-149, column 1.

Specific provisions of the Administrative Regulations Under the PCT and the corresponding provisions of the MPEP strongly support a finding of unity of invention among all of the claims in the present case

Unity of Invention is accepted as between claims to polypeptides and claims to the polynucleotides which encode them

Example 17, Part 2 of Annex B to the Administrative Instructions Under the PCT provides that unity of invention is accepted as between claims to polypeptides and claims to polynucleotides encoding those polypeptides. Those Examples are cited in MPEP section 1893.03(d) at page 1800-149, column 2 ("[n]ote also examples 1-17 of Annex B Part 2 of the PCT Administrative Instructions...")

Thus, in the present case, unity of invention exists at least as between claims drawn to polypeptides of SEQ ID NO:1-9 (*i.e.,* Claims 21, 22, 36 and 37) and as to claims drawn to polynucleotides which encode those polypeptides (*i.e.,* Claims 22-27 and 31-32).

Unity of invention exists with respect to dependent claims in the same claim category as the independent claim from which they depend

MPEP section 1850(A) and 1893.03(d), which recite the provisions of paragraph (c) of Part 1 (entitled "Instructions Concerning Unity of Invention") of Annex B (entitled "Unity of Invention") to the Administrative Instructions Under the PCT, provides:

> **(A) Independent and Dependent Claims.**
>
> Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims. By "dependent" claim is meant a claim which contains all the features of another claim and is in the same category of claim as that other claim (the expression "category of claim" referring to the classification of claims according to the subject matter of the invention claimed for example, product, process, use or apparatus or means, etc.).
>
> (i) If the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims. In particular, it does not matter if a dependent claim itself contains a further invention....

See MPEP section 1850(A) at page 1800-61. See also MPEP Appendix AI at page 53.

In the present case, Claims 22-27 and 36-37, all of which depend from Claim 21, are all directed to compositions of matter, *i.e.,* to products. Claims 22-27 and 36-37 contain all of the

features of independent Claim 21. Claim 32 depends from Claim 31, is directed to a composition of matter, *i.e.*, to products. Claim 32 contains all of the features of independent Claim 31. Further, as discussed above, there is unity of invention as between Claim 21 and Claim 31.

Unity of invention exists as between all of Applicants' claims

MPEP 1850 provides:

> Unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more special technical features. The term "special technical features" is defined as meaning those technical features that define a contribution which each of the inventions considered as a whole, makes over the prior art. The determination is made based on the contents of the claims as interpreted in light of the description and drawings. Annex B also contains examples concerning unity of invention.

Id at page 800-61.

MPEP 1893.03(d) similarly provides:

> A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature. The expression special technical features is defined as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art. For example, a corresponding technical feature is exemplified by a key defined by certain claimed structural characteristics which correspond to the claimed features of a lock to be used with the claimed key. Note also examples 1-17 of Annex B Part 2 of the PCT Administrative Instructions as amended July 1, 1992 contained in Appendix AI of the MPEP.

Id at page 1800-149.

In the present case, unity of invention exists among all of Applicants' claims. The sequences of the claimed polypeptides and the sequences of the claimed polynucleotides encoding those polypeptides are corresponding technical features which are common to all of Applicants claims, which serve to technically interrelate all of Applicants' claims, and which define the contribution over the prior art made by each of them. Thus, Applicants' claims are linked to form a single general inventive concept, and Applicants are therefore entitled to prosecute all of their pending claims in a single national stage application.

The sequences of the claimed polypeptides and the claimed polynucleotides encoding those polypeptides, are corresponding technical features that are common to all of Applicants' claims and that serve to technically interrelate them

Applicants' claims recite *inter alia* the polypeptides of SEQ ID NO:1-9, and polynucleotides encoding those polypeptides, which include the polynucleotides of SEQ ID NO:10-18. The sequences of the claimed polypeptides and corresponding polynucleotides are common to all of Applicants' claims, given that each claim refers to one or both either explicitly or implicitly, by virtue of depending from a claim which makes an explicit reference to the sequences of the claimed polypeptides or claimed polynucleotides.

Moreover, the sequences of the claimed polypeptides and corresponding polynucleotides serve to technically interrelate all of Applicants' claims. Applicants' composition of matter Claims 21-27, 30-32, and 36-37) are drawn to either the polypeptides or polynucleotides themselves (21 and 22, drawn to polypeptides, and 23-25 and 31-32, drawn to polynucleotides), to compositions of matter which comprise the polypeptides or polynucleotides as one element (26 and 27, drawn to recombinant polynucleotides and transformed cells, respectively, and 36-37, drawn to pharmaceutical compositions), or to compositions of matter wherein the sequences of the claimed polypeptides functionally limit the claimed subject matter (Claim 30, drawn to an antibody which specifically binds a polypeptide of Claim 21).

In Applicants' method Claims 28-29, 33-35, and 38-40), the claimed polypeptides or polynucleotides serve as either the product of the claimed method (Claims 28-29, drawn to methods of polypeptide production) and/or as a reagent for performing the method (Claims 38, 39, and 40, drawn, respectively, to a method of screening a compound for effectiveness as an agonist of, a method of screening a compound for effectiveness as antagonist of, and a method of screening for a compound that specifically binds, a polypeptide of Claim 21; and Claims 33-35 drawn to methods of detecting a target polynucleotide in a sample).

Therefore, the sequences of the claimed polypeptides and polynucleotides are corresponding technical features which are common to all of Applicants' claims, and which serve to technically interrelate them.

The Restriction Requirement Among Individual Polypeptide and Polynucleotide Sequences

Applicants elect, with traverse, to prosecute that portion of Claims 21-29, 31-32, and 36-37 directed to the polypeptide sequence of SEQ ID NO:5 and the polynucleotide sequence of SEQ ID NO:14. Applicants traverse the restriction requirement among individual polypeptide and polynucleotide sequences for at least the following reasons.

The Examiner alleged that the claims as filed "constitute a recitation of an implied, mis-joined Markush group that contains multiple, independent and distinct inventions. *Each of the polypeptides and nucleic acids are independent and distinct* because no common structural or functional properties are shared. Accordingly , these claims are subject to lack of unity under PCT Rule 13.1. Upon election of one of Groups I-VII, Applicant is additionally required to elect a single polypeptide or nucleic acid." (Office Action, page 3, italics added.)

It is unclear to Applicants from the preceding quotation whether the Examiner considers even a polypeptide and the polynucleotide encoding the polypeptide as "independent and distinct" inventions. Applicants request clarification from the Examiner as this position would appear to contravene Example 17, Part 2 of Annex B to the Administrative Instructions Under the PCT which provides that unity of invention is accepted as between claims to polypeptides and claims to polynucleotides encoding those polypeptides. If indeed the Examiner considers a polypeptide and the polynucleotide encoding the polypeptide as "independent and distinct" inventions, this appears also to be in conflict with Group I which as it stands includes both the "purified polypeptide" and the "polynucleotide encoding it" according to the Office Action on page 2.

With respect to the polypeptides of SEQ ID NO:1-9 and the polynucleotides of SEQ ID NO:10-18), section D of MPEP section 1850, which recites the provisions of paragraph (f) of Part 1 (entitled "Instructions Concerning Unity of Invention") of Annex B (entitled "Unity of Invention") to the Administrative Instructions Under the PCT, provides:

> ***D. "Markush Practice"***
>
> The situation involving the so-called Markush practice wherein a single claim defines alternatives (chemical or non-chemical) is also governed by PCT Rule 13.2. In this special situation, the requirement of a technical interrelationship and

the same or corresponding special technical features as defined in PCT Rule 13.2, shall be considered to be met when the alternatives are of a similar nature.

(i) When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled:

(A) All alternatives have **a common property or activity; AND**

(B)(1)A common structure is present, *i.e.*, **a significant structural element is shared by all of the alternatives; OR**

(C)(2) In cases where the common structure cannot be the unifying criteria, **all alternatives belong to a recognized class of chemical compounds** in the art to which the invention pertains.

(ii) In paragraph (B)(1), above, the words "significant structural element is shared by all of the alternatives" refer to cases where the compounds share **a common chemical structure** which **occupies a large portion of their structures**, or in case the compounds have in common only a small portion of their structures, the commonly shared structure **constitutes a structurally distinctive portion** in view of existing prior art. The structural element may be **a single component OR a combination of individual components linked together.**

(iii) In paragraph (C)(2), above, the words "recognized class of chemical compounds" mean that there is an expectation from the knowledge in the art that members of the class will behave in the same way in the context of the claimed invention. In other words, each member could be substituted one for the other, with the expectation that the same intended result would be achieved.

(iv) The fact that the alternatives of a Markush grouping can be differently classified shall not, taken alone, be considered to be justification for a finding of a lack of unity of invention.

(v) When dealing with alternatives, if it can be shown that at least one Markush alternative is not novel over the prior art, the question of unity of invention shall be reconsidered by the examiner. Reconsideration does not necessarily imply that an objection of lack of unity shall be raised.

See MPEP at pages 1800-61 to -62.

Contrary to the Examiner's allegation, the polypeptides of SEQ ID NO:1-9 and polynucleotides of SEQ ID NO:10-18 claimed by Applicants are alternatives of a similar nature, and should therefore be examined in a single application. The pending claims recite proper Markush groups, contrary to the Examiner's unsupported allegation.

Applicants submit that the polypeptides of SEQ ID NO: 1-9 are alternatives of a similar nature in that all have been identified by Applicants as SOCS proteins on the basis of

the presence of the characteristic "SOCS box" structural domain. See the Specification, e.g., at Table 2 and pages 1-3. As such, the polypeptides of SEQ ID NO: 1-9 share the common property/activity of being SOCS box proteins involved in cell signaling.

The polynucleotides of SEQ ID NO:10-19 are alternatives of a similar nature in that all encode polypeptides which contain the "SOCS box" domain.

Therefore, Applicants respectfully request that the Examiner withdraw the restriction requirement among individual polypeptide and polynucleotide sequences, and examine together those claims which relate to SEQ ID NO:1-9 and SEQ ID NO:10-18.

It is noted that, while Applicants have canceled and not repeated new versions of the claims of Groups IV, V, VI, and VII, Applicants expressly assert that these claims have been canceled for reasons relating to cost and efficiency of prosecution of the presently elected claims, and not for reasons relating to patentability. Applicants further expressly reserve the right to pursue the subject matter of those canceled claims, or any other subject matter disclosed but not herein claimed, in a later continuation or divisional application.

Applicants believe that no fee is due with this communication. However, if the USPTO determines that a fee is due, the Commissioner is hereby authorized to charge Deposit Account No. 09-0108.

Respectfully submitted,

INCYTE GENOMICS, INC.

Date: November 27, 2002

Susan K. Sather

Susan K. Sather
Reg. No. 44,316
Direct Dial Telephone: (650) 845-4646

3160 Porter Drive
Palo Alto, California 94304
Phone: (650) 855-0555
Fax: (650) 849-8886

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

Claims 1-20 have been canceled.

Claims 21-40 have been added.